SYSTEM, METHODS AND KITS FOR DIAGNOSIS AND TREATMENT OF FEMALE PATTERN HAIR LOSS

CROSS-REFERENCE

[0001] This application is a non-provisional utility application which claims priority to U.S. provisional application 63/004,159 filed Apr. 2, 2020, the entire contents of which are incorporated herein by reference.

FIELD

[0002] The present invention relates to methods and compositions for the treatment of female pattern hair loss. Topical compositions containing soy isoflavones are described as well as a method of treatment. Additionally, a method for predicting female pattern hair loss and the likelihood a soy isoflavone treatment will be effective for treating hair loss are described.

BACKGROUND

[0003] Female pattern hair loss (FPHL), also termed female androgenetic alopecia, is the progressive miniaturization of hair follicles on the female scalp. It is a frequently occurring condition affecting 30-40% of the female population by the age of 60. It is characterized by diffuse thinning of the crown region of the scalp while the frontal hairline remains intact. Addition signs of FPHL include wider thinning on the frontal scalp giving the balding area a triangular shaped figure resembling a "Christmas tree". FPHL is the most common form of hair loss. The Sinclair scale for female pattern hair loss is commonly used to assess the degree of hair loss. Female pattern hair loss is hereditary but dependent on hormones to influence its development.

[0004] 2% topical minoxidil is the only US FDA approved drug for the treatment of FPHL. It is estimated that 13-20% of FPHL patients experience a moderate increase in hair regrowth when using a 2% minoxidil mono-therapy. 5% minoxidil solutions are also used as a treatment for FPHL. Clinical trials suggest that 5% minoxidil has better efficacy than 2% minoxidil based on the average change in nonvellus hair count. Clinical studies in men suggest that approximately 40% of patients experience hair growth when using 5% minoxidil. The risk for adverse events with both 2% and 5% minoxidil is low; however, irritant dermatitis, allergic contact dermatitis, and hypertrichosis have been reported. Due to the prolonged treatment time required to elicit a therapeutic response (approximately 6 months) combined with the variable efficacy of minoxidil in the general population, an alternative treatment would have significant clinical utility.

[0005] Soy isoflavones are phytoestrogens found naturally in soybeans. Phytoestrogens are plant-derived compounds that have estrogen-like biologic activity. The most abundant isoflavones in soy beans are genistein and daidzein. Because of the ability to bind to the estrogen receptor, isoflavones have been studied as possible treatments for conditions mediated by the estrogen receptor, e.g., breast cancer and endometriosis.

[0006] The effects of isoflavones on estrogen mediated disease have had conflicting reports in literature. For example, isoflavones intake has been reported to have a protective effect against postmenopausal breast cancer in a Japanese population, while high serum isoflavone levels were associated with increased breast cancer rate in a United Kingdom population. It is clear that the mechanism of isoflavone interaction with estrogen mediated disease is complicated and likely dependent on genetic predisposition.

SUMMARY

[0007] Compositions and methods are disclosed herein for treating female pattern hair loss (FPHL) with isoflavones. Because of the inter-individual variation in phytoestrogen sensitivity, the treatment method will require a diagnostic test to guide the selection of a phytoestrogen and a dosage. Additionally, a method is described to predict the risk that a subject will develop FPHL and the likelihood that an isoflavone will have a prophylactic effect to prevent FPHL.

[0008] In an exemplary embodiment, a method of treating alopecia in a subject in need thereof involves: applying to the scalp of the subject a composition containing a phytoestrogen.

[0009] In some embodiments, after applying the composition containing a phytoestrogen, the subject subsequently applies a topical minoxidil composition.

[0010] In some embodiments, the phytoestrogen is an isoflavone.

[0011] In some embodiments, the isoflavone is any one or combination of daidzein, genistein, glycitein, formononetin, biochanin A, daidzin, genistin, glycitin, ononin, sissotrin, acetyldaidzin, acetylgenistin, acetylglycitin, malonyldaidzin, malonylgenistin, malonylglycitin, malonylononin, or malonylsissotrin.

[0012] In an exemplary embodiment, a method to determine whether a subject will respond to or benefit from a phytoestrogen based treatment for alopecia involves: measuring a variant of SNP rs1013718 in the ESR2 gene of the subject.

[0013] In some embodiments, the method involves: collecting a DNA sample from the subject; extracting the DNA from the sample; amplifying DNA segments of the extracted DNA corresponding to a variant of SNP rs1013718 in the ESR2 gene; and analyzing the data to determine the SNP rs1013718 variant of the subject.

[0014] In some embodiments, the variant of SNP rs1013718 is any one or combination of "CC", "CT" or "TT".

[0015] In some embodiments, the method involves: determining that the subject will respond to or benefit from the phytoestrogen based treatment when the variant is "CC".

[0016] In some embodiments, the method involves: determining that the subject has an increased risk of developing female pattern hair loss when the variant is "CC".

[0017] In some embodiments, the method involves: determining that the subject has a lower risk of developing female pattern hair loss when the variant is "CT" or "TT", as compared to the risk of developing female patter hair loss when the variant is "CC".

[0018] In some embodiments, the DNA sample is a saliva sample.

[0019] In some embodiments, after extracting the DNA from the sample, the DNA is purified and subsequently quantified.

[0020] In some embodiments, the DNA is amplified by a real-time polymerase chain reaction protocol.

[0021] In some embodiments, the DNA is analyzed in an allelic discrimination plot.